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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,938	06/25/2001	Graham P. Allaway	50875-DA/JPW/SHS	9272

7590 05/05/2004  
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EXAMINER

BROWN, TIMOTHY M

ART UNIT PAPER NUMBER

1648

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/888,938	Applicant(s) ALLAWAY ET AL.	
	Examiner Tim Brown	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 June 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 51-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>August 13, 2001</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The preliminary amendment submitted June 25, 2001 cancelled claims 1-50, and added new claims 51-56. Claims 51-56 have been examined.

#### ***Information Disclosure Statement***

The information disclosure statements submitted on August 13, 2001, March 31, 2003 and April 21, 2003 were filed after the mailing date of this on June 25, 2001. These submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the Examiner has considered the references submitted by Applicant.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 51-56 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The invention is directed to “an antibody or a portion of an antibody” capable of binding a chemokine receptor. An antibody, or a portion of an antibody such as an amino acid, is a product of nature. Accordingly, claims 51-56 are directed to non-statutory subject matter. Amending the claims to recite “[a] purified antibody or a purified portion of an antibody” would overcome this rejection.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 51 and 52-55 are rejected under 35 U.S.C. 102(b) as being anticipated by “Hirata” (Hirata Y. “Characterization of IL-6 Receptor Expression by Monoclonal and Polyclonal Antibodies” The Journal of Immunology (November 1, 1989) pp. 2900-2906)**

Regarding claim 51, Hirata teaches an antibody or a portion of an antibody capable of binding to a chemokine receptor on the surface of a CD4<sup>+</sup> cell (p. 2901 and 2905).

Regarding claim 51, Hirata teaches an antibody or a portion of an antibody capable of binding to a CCR5 chemokine receptor on the surface of a CD4<sup>+</sup> cell (Id.).

Regarding claim 53, Hirata teaches the antibody or a portion of an antibody of claim 51 or 52, wherein the CD4<sup>+</sup> cells is a PM-1 cell (Id.).

Regarding claim 54, Hirata teaches the antibody or a portion of an antibody of claim 51 or 52, wherein the CD4<sup>+</sup> cell is a primary CD4<sup>+</sup> T-cell (Id.).

Regarding claim 55, Hirata teaches the antibody or a portion of an antibody of claim 51 or 52, wherein the CD4<sup>+</sup> cell is a PMBC cell (Id.).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

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which it is most nearly connected, to make and/or use the invention without undue experimentation.

The determination of whether experimentation is “undue” weighs a number of factors. These factors include: breadth of the claims; the state of the prior art; the level of predicatability in the art; the existence of working examples; and the quantity of experimentation that is needed to make and use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

In the present case, Applicant’s invention is broadly drawn to an antibody, or a portion of an antibody, that is capable of binding to the CCR5 receptor. Giving the claims their broadest reasonable interpretation “a portion of an antibody” reads on a single amino acid. The state of the art does not recognize the interaction of the CCR5 receptor with a single amino acid. Rather, as noted by Applicants, chemokine receptors interact with a number of known ligands including RANTES, MIP-1-a and MIP-1-p (specification p. 11, lines 15-19). The level of predictability in the art would not permit one of ordinary skill to determine those portions of an antibody that would interact with the CCR5 receptor. This results from the fact that whether a protein interacts with an antibody or other ligand is determined by distinct conformational properties that make the interaction highly specific. The amount of direction provided by Applicant’s specification would not allow one of ordinary skill to overcome the lack of predictability in the binding properties of CCR5. This results from Applicant’s failure to show any working examples of CCR5 interacting with either an antibody, or a portion of an antibody; Applicant’s specification only demonstrates the interaction of CCR5 with a number of chemokine proteins. One of ordinary skill would therefore have to perform significant experimentation in order to identify

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the broad range of antibodies, or portions of antibodies, that are capable of binding CCR5.

Based on the foregoing, Applicant's specification would not enable one of ordinary skill to make and use Applicant's invention without undue experimentation.

Claims 51-56 are further rejected under 35 U.S.C. 112, first paragraph for failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. In the present case, Applicant's invention is directed to an antibody or portion of an antibody capable of binding to the CCR5 receptor. However, Applicant's specification does not disclose any experimentation wherein a CCR5 antibody, or portion of a CCR5 antibody, was produced or used. Accordingly, Applicant has not shown possession of the claimed invention at the time the application was filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 52 recites "[t]he antibody or portion of an antibody" in the first line of the claim. There is no antecedent basis for this limitation in the claim.

Claims 51-52 are also indefinite in their recitation of "a portion of an antibody." As noted above, "a portion of an antibody" reads on a single amino acid. A single amino acid is incapable of recognizing specific epitopes within a chemokine receptors. Thus, it is unclear how "a portion of an antibody" is capable of binding the claimed chemokine receptors.

Claim 55 is further rejected under 35 U.S.C. 112, second paragraph for the recitation of a "PMBC" cell. This acronym requires clarification within the claim before it can be recited.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tim Brown  
Examiner  
Art Unit 1648

tmb

*Sharon Foley*  
*Patent Examiner, 1648*